510(K) SUMMARY

MAR 21 2003

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA1990) and with 21 CFR Part 807.92

K030590

1. Name & Contact Information of Manufacturer

   Hitachi Chemical Diagnostics
   630 Clyde Court, Mountain View, CA 94043
   (650) 961 – 5501

2. Contact Person

   Mary Ann Du Brock
   Director Quality Assurance & Regulatory Affairs

3. Establishment Registration Number

   2936856

4. Product Name

Proprietary Name:	CLA® Allergen-Specific IgE Assay – Latex Allergen k82
Common Name:	Chemilumnescent Immunoassay for the detection of Latex Allergen
Classification Name:	System, Test, Radioallergosorbent (RAST) Immunological

5. Product Classification

Product Name	Product Code	Class	CFR
CLA® Allergen-Specific IgE Assay – Latex Allergen k82	82 DHB	II	866.5750

6. Substantial Equivalence to:

   a. Hitachi Chemical Diagnostics, formerly MAST Immunosystems, CLA Allergen Specific IgE Assay System (K914850)
   b. UniCAP Specific IgE FEIA Assay, Latex Allergen (K972068)

7. Device Description

   a. The CLA® Allergen-Specific IgE Assay is a solid phase in vitro test used for the semi quantitative determination of multiple circulating allergen-specific IgE concentrations in human serum. This submission is to supplement the compliment of available tests with the addition of the Latex allergen.

8. Intended Use

   The CLA® Allergen-Specific IgE Assay is a single use in vitro test for the semi quantitative determination of circulating allergen-specific IgE antibodies in human serum.

9. Summary of Testing

Serum samples from a total of 196 patients were tested at three clinical sites using the CLA Allergen-specific IgE Assay for latex. Ninety-five (95) of these patients were diagnosed as clinically allergic to latex and tested positive while the remaining 101 patients were clinically negative. All samples were tested in parallel with Pharmacia UniCAP Specific IgE FEIA Assay, Latex Allergen the predicate 510(k) cleared, and commercially available latex specific IgE assay.

The comparison data show that determination of specific IgE to latex with CLA® Allergen-Specific IgE Assay has an excellent clinical performance and is substantially equivalent to Pharmacia UniCAP Specific IgE FEIA Assay, Latex Allergen, the legally marketed predicate device.

Hitachi CLA-1 Allergen Specific IgE vs. Pharmacia UniCAP Specific IgE FEIA for Latex Allergen k82

Hitachi CLA	Negative	Positive
Positive	9	86
Negative	92	9
	Pharmacia CAP	

SENSITIVITY %	90.53
SPECIFICITY %	91.09
EFFICIENCY %	90.82

10. Conclusion

The comparison data show that determination of specific IgE to latex with CLA® Allergen-Specific IgE Assay has an excellent clinical performance and is substantially equivalent to Pharmacia UniCAP Specific IgE FEIA Assay, Latex Allergen, the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 21 2003

Ms. Mary Ann Du Brock
Director Quality Assurance & Regulatory Affairs
Hitachi Chemical Diagnostics
630 Clyde Court
Mountain View, CA 94043-2239

Re: k030590
Trade/Device Name: CLA® Allergen-Specific IgE Allergy System
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB
Dated: February 21, 2003
Received: February 25, 2003

Dear Ms. Du Brock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K030590

Name: CLA® Allergen-Specific IgE Allergy System

Indications for Use:

The CLA® Allergen-Specific IgE Assay is a single use *in vitro* test for the semi quantitative determination of circulating allergen-specific IgE concentrations in human serum.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

J P Reeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030590